CMS Manual System	Department of Health & Human Services (DHHS)
Pub. 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)

Transmittal 532	Date: APRIL 25, 2005

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CHANGE REQUEST 3775

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SUBJECT: Abarelix for Treatment of Prostate Cancer

I. SUMMARY OF CHANGES: The Centers for Medicare & Medicaid Services is extending national coverage for the use of abarelix (Plenaxis™) as a palliative treatment in patients with advanced symptomatic prostate cancer: (1) in whom gonadotropin-releasing hormone (GnRH) therapy is not appropriate; (2) who decline surgical castration; and, (3) who present with one of the following: (a) risk of neurological compromise due to metastases; (b) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease; or, (c) severe bone pain from skeletal metastases persisting on narcotic analgesia.

The revision to section 110.19 of Pub. 100-03 is a national coverage determination. For further details on coverage, refer to that publication.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: March 15 2005
IMPLEMENTATION DATE: May 25, 2005

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

X	Business Requirements
	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-04	Transmittal: 532	Date: April 25, 2005	Change Request 3775

SUBJECT: Abarelix for the Treatment of Prostate Cancer

I.   GENERAL INFORMATION

A.   Background: An estimated 230,000 new cases of prostate cancer occurred in the United States during 2004. Treatment options vary once the disease is diagnosed depending on age, stage of the cancer, and other individual medical conditions. Surgery (e.g., radical prostatectomy) or radiation is typically used for early-stage disease. Hormonal therapy, chemotherapy, and radiation (or combinations of these treatments) are used for more advanced disease. Prostate cancer is androgen-dependent. In recent years, hormonal therapy has evolved from orchiectomy and estrogens to the use of synthetic drugs known as gonadotropin-releasing hormone (GnRH) agonists or analogues. GnRH agonists include drugs such as leuprolide (Lupron™) and goserelin (Zoladex™). In contrast with GnRH agonists, newer compounds such as abarelix (Plenaxis™) are thought to be devoid of agonist activity and to lack an initial androgen-stimulating effect and are thus considered GnRH receptor antagonists. Abarelix has been proposed as a substitute for GnRH agonists with and without antiandrogens in the treatment of patients with advanced prostate cancer for whom a surge in androgen blood levels may pose a risk of "clinical flare." For this indication, abarelix is the first GnRH receptor antagonist to receive approval from the Food and Drug Administration (FDA).

B.   Policy: Effective March 15, 2005, the Centers for Medicare & Medicaid Services is extending national coverage for the use of abarelix (Plenaxis™) as a palliative treatment in patients with advanced symptomatic prostate cancer: (1) in whom gonadotropin-releasing hormone (GnRH) therapy is not appropriate, (2) who decline surgical castration, and, (3) who present with one of the following: (a) risk of neurological compromise due to metastases, (b) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (c) severe bone pain from skeletal metastases persisting on narcotic analgesia.

II.   BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)					
		F I	R H	C a	D M	Shared System Maintainers	Other

						F I S S	M C S	V M S	C W F	
3775.1	Effective for dates of service on or after March 15, 2005, contractors shall pay claims for abarelix with HCPCS code J0128 when used for treatment of patients with prostate cancer according to section 110.19 of Pub. 100-03, National Coverage Determinations (NCD) Manual.	X		X		X	X	X		
3775.2	FI's shall pay claims with the following TOBs for the use of abarelix in the treatment of patients with prostate cancer according to the NCD: • 11x • 13x • 18x • 83x • 85x	X								
3775.3	FI's shall pay claims with revenue code 0636 (drugs requiring detailed coding) when used for the treatment of patients with prostate cancer according to the NCD.	X								
3775.4	Contractors shall apply appropriate payment methodologies, rates, and payment policies regarding drugs in general, including appropriately applying policies related to the administration of drugs and incident to services.	X		X		X	X	X		
3775.5	Contractors shall pay for covered routine costs associated with the use of abarelix in the treatment of patients with prostate cancer according to the NCD.	X		X		X	X	X		
3775.6	Contractors shall pay separately for abarelix chemotherapy injections when billed using an appropriate chemotherapy administration procedure code in addition to the visit furnished on the same day.	X		X		X	X	X		
3775.7	Contractors shall edit for any appropriate prostate cancer diagnosis code for payment of abarelix according to the NCD.	X		X		X	X	X		
3775.8	Contractors shall, commencing with the implementation date of the change request, deny claims for uses of abarelix that are not covered under the NCD for services performed on or after the March 15, 2005. Contractors	X		X		X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	shall not search for and adjust claims that have been paid prior to the implementation date of the NCD for services performed on or after the March 15, 2005.									
3775.9	Intentionally left blank.									
3775.10	Contractors shall deny claims if coverage criteria at Pub 100-03, NCD Manual, section 110.19, are not met by returning an appropriate remittance advice and including MSN message 6.5 (Medicare cannot pay for this injection because one or more requirements for coverage were not met), reason code 47, (This (these) diagnosis(es) is (are) not covered, missing, or are invalid), and remark code M76 (missing/incomplete/invalid diagnosis or condition).	X		X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3775.11	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "Medlearn Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next	X		X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.									

IV.   SUPPORTING   INFORMATION   AND   POSSIBLE   DESIGN CONSIDERATIONS

A.   Other Instructions: N/A

X-Ref Requirement #	Instructions

B.   Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C.   Interfaces: N/A

D.   Contractor Financial Reporting /Workload Impact: N/A

E.   Dependencies: N/A

F.   Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: March 15, 2005 **Implementation Date:** May 25, 2005 **Pre-Implementation Contact(s):** Bill Ruiz (Part A claims), 410-786-9283, Thomas Dorsey (Part B claims)(410)786-7434 Kate Tillman(coverage), 410-786-9252, Pat Brocato-Simons (coverage), 410-786-0261 **Post-Implementation Contact(s):** Appropriate CMS Regional Office	**No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.**

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